

CLAIMS:

1. A method of manufacturing a hearing aid comprising the steps of:
 - a) placing a moldable material in the ear canal of a patient to cast a form;
 - 5 b) using the form to form a hollow shell with an outer surface that approximates the shape of the patient's ear canal, the shell being of a soft polymeric material;
 - c) providing a mounting member;
 - d) mounting electronic hearing aid components to the mounting member;
 - e) joining the mounting member to the hollow shell to define a mold cavity;
 - 10 f) filling the shell with a soft polymeric material that substantially encapsulates at least one of the electronic components and bonds to the mounting member;
 - g) wherein the combination of shell, electronic components and soft polymeric material define a soft structure that is compliant to ear canal movement during use.
2. The method of claim 1 further comprising the step of eliminating substantially all
15 void space between the shell and the electronic components with the filling in step "f" so that feedback is minimized.
3. The method of claim 1 wherein step "c" comprises providing a mounting member that is a rigid plastic member.
4. The method of claim 1 wherein step "c" comprises providing a mounting member
20 that is an acrylic member.
5. The method of claim 1 wherein in step "c" the mounting member has medial and lateral side portions.
6. The method of claim 5 wherein in step "d" electronic hearing aid components are attached to the medial side portion of the mounting member.
- 25 7. The method of claim 1 wherein in step "f" filling includes encapsulating at least a receiver electronic hearing aid component.
8. The method of claim 1 wherein step "f" comprises filling the shell with a soft silicone material that substantially encapsulates at least one of the electronic components.
9. The method of claim 1 further comprising placing a bonding layer between the
30 mounting member and soft polymeric material.
10. The method of claim 1 wherein in step "f" the soft polymeric material has a

hardness of between about 3 and 55 Durometer Shore A.

11. A method of manufacturing a hearing aid comprising the steps of:

a) forming a hollow shell with an inside surface that approximates the shape of the human ear canal, the shell being of a soft polymeric material;

b) providing a mounting member;

c) mounting electronic hearing aid components to the mounting member;

d) joining the hollow shell to the mounting member to define a mold cavity;

e) filling the mold cavity with a soft polymeric material that substantially encapsulates the electronic components and bonds to the mounting member;

f) eliminating substantially all void space between the shell and the electronic components with the filling in step "e";

g) allowing the soft polymeric material to cure;

h) wherein the combination of electronic components and soft polymeric material define a soft structure that is compliant to ear canal movement during use.

12. The method of claim 11 further comprising the step of removing the shell.

13. The method of claim 11 further comprising the steps of making an impression of the user's ear canal to construct a form and using the form to shape the inside surface of the hollow shell.

14. The method of claim 11 further comprising the step of using a male mold to form the inside surface of the hollow shell.

15. The method of claim 11 wherein the shell and mounting members are temporarily joined with a seal in step "d".

16. The method of claim 11 wherein in step "e" at least a receiver is encapsulated.

17. The method of claim 11 wherein in step "e" at least a receiver and wiring harness are encapsulated.

18. The method of claim 11 further comprising the step of using a bonding enhancer to join the soft polymeric material to the mounting member.

19. The method of claim 11 wherein in step "b" the mounting member has a hard plastic surface and further comprising the step of using a bonding layer to join the soft polymeric material to the mounting member.

20. The method of claim 18 wherein the bonding layer includes multiple coatings

applied to the mounting member.

21. The method of claim 11 wherein in step "b" the mounting member is a hard plastic and in step "e" the soft polymeric material includes silicone.

22. A method of manufacturing a hearing aid comprising the steps of:

- a) making a male mold that accurately conforms to the shape of a patient's ear canal;
- b) using the male mold to form a female mold with an inside surface that generally

duplicates the shape of the male mold and at least a section of the patient's ear canal;

- c) providing a mounting member;
- d) mounting electronic hearing aid components to the mounting member;
- e) attaching the mold to the mounting member to define a cavity;
- f) filling the cavity with a soft polymeric material that substantially encapsulates at

least one of the electronic components and bonds to the mounting member; and

g) wherein the combination of the shell, soft polymeric material, and electronic component define a soft structure that is compliant to ear canal movement during use.

23. The method of claim 22, wherein the hearing aid is sized to fit completely in the ear canal of the patient.

24. The method of claim 1, wherein the hearing aid is sized to fit completely in the ear canal of the patient.

25. The method of claim 11, wherein the hearing aid is sized to fit completely in the ear canal of the patient.

26. A method of manufacturing a hearing aid comprising the steps of:

- a) providing a mounting member with at least one opening;
- b) using the form to form a hollow shell with an outer surface that approximates the

shape of the patient's ear;

- c) joining the mounting member to the hollow mold having a mold cavity;
- d) placing a vent tube inside the mold cavity;
- e) placing an insert inside the mold cavity, the insert having a configuration that

generally simulates a hearing aid components assembly;

f) filling the shell with a soft polymeric material that sets to form a soft-solid structure that substantially encapsulates the vent tube and the insert and bonds to the mounting member;

- g) removing the insert from the soft, solid structure to form a void space; and
- h) placing a hearing aid component assembly into the void space.

27. The method of claim 26 further comprising the step of eliminating substantially all void space between the mold and the hearing aid components with the filling step so that feedback is minimized.

28. The method of claim 26 wherein step "a" comprises providing a mounting member that is a rigid plastic member.

29. The method of claim 26 wherein step "a" comprises providing a mounting member that is an acrylic member.

30. The method of claim 26 wherein in step "a" the mounting member has medial and lateral side portions.

31. The method of claim 30 wherein the electronic hearing aid components are attached to the medial side portion of the mounting member.

32. The method of claim 26 wherein the hearing aid components assembly includes at least one receiver and filling includes encapsulating at least a receiver simulated insert section.

33. The method of claim 26 wherein step "f" comprises filling the shell with a soft silicone material.

34. The method of claim 26 further comprising placing a bonding layer between the mounting member and soft polymeric material.

35. The method of claim 1 further comprising placing a bonding material on the vent tube.

36. The method of claim 26 wherein in step "f" the soft polymeric material has a hardness of between about 3 and 40 Durometer Shore A.

37. A method of manufacturing a hearing aid comprising the steps of:

a) forming a hollow shell with an inside surface that approximates the shape of the human ear canal;

b) providing a mounting member;

c) joining the hollow shell to the mounting member to define a mold cavity;

d) placing a vent tube and an insert inside the mold cavity;

e) coating the vent tube with a bonding agent;

f) filling the mold cavity with a soft polymeric material that substantially

encapsulates the vent tube and insert;

g) eliminating substantially all void space between the shell and the components with the filling in step "g";

h) allowing the soft polymeric material to cure;

i) removing the insert to leave a void space inside the soft polymeric material;

j) placing a hearing aid component assembly inside the void space;

k) wherein the combination of components and soft polymeric material define a soft structure that is compliant to ear canal movement during use.

38. The method of claim 36 further comprising the step of removing the shell.

39. The method of claim 36 further comprising the steps of making an impression of the user's ear canal to construct a form and using the form to shape the inside surface of the hollow shell.

40. The method of claim 36 further comprising the step of using a male mold to form the inside surface of the hollow shell.

41. The method of claim 36 wherein the shell and mounting members are temporarily joined with a seal in step "c".

42. The method of claim 36 wherein in step "f" at least a receiver shaped insert section is encapsulated.

43. The method of claim 36 wherein in step "f" at least receiver and wiring harness shaped insert sections are encapsulated.

44. The method of claim 36 wherein in step "f" at least receiver, wiring harness and battery compartment shaped insert sections are encapsulated.

45. The method of claim 36 further comprising the step of using a bonding enhancer to join the soft polymeric material to the mounting member.

46. The method of claim 36 wherein in step "b" the mounting member has a hard plastic surface and further comprising the step of using a bonding layer to join the soft polymeric material to the mounting member.

47. The method of claim 44 wherein the bonding layer includes multiple coatings applied to the mounting member.

48. The method of claim 36 wherein in step "b" the mounting member is a hard plastic and in step "f" the soft polymeric material includes silicone.

49. A method of manufacturing a hearing aid comprising the steps of:

a) making a mold with an inside surface that generally duplicates the shape of and
at least a section of a patient's ear canal;

b) attaching the mold to a mounting member to define a mold cavity;

5 c) placing a vent tube and an insert inside the mold cavity;

d) filling the mold cavity with a soft polymeric material that substantially
encapsulates the vent tube and the insert;

e) removing the insert after the material cures to leave a void space;

f) placing a hearing aid component assembly insert into the void space;

10 g) wherein the combination of shell soft polymeric material and hearing aid
component assembly define a soft structure that is compliant to ear canal movement during use.

50. The method of claim 49, wherein the hearing aid is sized to fit completely in the
ear canal of the patient.

15 51. The method of claim 26, wherein the hearing aid is sized to fit completely in the
ear canal of the patient.

52. The method of claim 37, wherein the hearing aid is sized to fit completely in the
ear canal of the patient.